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and JOHNSON & JOHNSON

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

UNITED STATES OF AMERICA, STATES
OF CALIFORNIA, COLORADO,
CONNECTICUT, DELAWARE, FLORIDA,
GEORGIA, HAWAII, ILLINOIS, INDIANA,
IOWA, LOUISIANA, MICHIGAN,
MINNESOTA, MONTANA, NEVADA,
NEW JERSEY, NEW MEXICO, NEW
YORK, NORTH CAROLINA, OKLAHOMA,
RHODE ISLAND, TENNESSEE, TEXAS,
VERMONT, AND WASHINGTON; THE
COMMONWEALTHS OF
MASSACHUSETTS AND VIRGINIA; and
THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

vs.

JANSSEN BIOTECH, INC., JANSSEN
ONCOLOGY, INC., JANSSEN RESEARCH
& DEVELOPMENT, LLC, and JOHNSON &
JOHNSON,

Defendants.

Case No.: 3:17-cv-07250-JST

**DEFENDANTS' NOTICE OF REQUEST,
REQUEST, AND MEMORANDUM OF
POINTS AND AUTHORITIES IN
SUPPORT OF REQUEST FOR JUDICIAL
NOTICE IN SUPPORT OF DEFENDANTS'
MOTION TO DISMISS AMENDED
COMPLAINT**

Judge: Hon. Jon S. Tigar

Date: May 16, 2019

Time: 2:00 PM

Place: Courtroom 9, 19th Floor, Phillip Burton
Federal Building

NOTICE OF REQUEST AND REQUEST

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT on May 16, 2019 at 2:00 PM, or as soon thereafter as counsel may be heard in the above-entitled Court located at 450 Golden Gate Avenue, San Francisco, California 94102, Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson, pursuant to Federal Rule of Evidence 201 and in connection with the concurrently filed Motion to Dismiss, will and hereby do respectfully request that the Court take judicial notice of the following Exhibits, true and correct copies or excerpts of which are attached:

Exhibit A – U.S. Patent No. 5,604,213 (issued Feb. 18, 1997).

Exhibit B – U.S. Patent No. 8,822,438 (issued Sept. 2, 2014).

Exhibit C – Applicant Arguments, Notice of Appeal, and Other Reference-Appeal Documents, submitted June 4, 2013, for U.S. Patent Application No. 13/034,430 (filed Feb. 24, 2011), *available at* <https://portal.uspto.gov/pair/PublicPair>.

Exhibit D – Petition, *Amerigen Pharm., Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286 (P.T.A.B. Dec. 12, 2015), *available at* <https://ptab.uspto.gov/#/login>.

Exhibit E – Petition, *Mylan Pharm., Inc. v. Janssen Oncology, Inc.*, IPR2016-01332 (P.T.A.B. June 30, 2016), *available at* <https://ptab.uspto.gov/#/login>.

Exhibit F – Petition, *Wockhardt Bio AG v. Janssen Oncology, Inc.*, IPR2016-01582 (P.T.A.B. Aug. 10, 2016), *available at* <https://ptab.uspto.gov/#/login>.

Exhibit G – Michael S. Cookson et. al, *Castration-Resistant Prostate Cancer: AUA Guideline*, AMERICAN UROLOGY ASSOCIATION EDUCATION AND RESEARCH, INC. (2013).

Exhibit H – GSA Drugs, Pharmaceuticals & Hematology Related Products Solicitation, 01 – Solicitation Document, Standing Solicitation No. M5-Q50A-03-R8.

Exhibit I – Specification, submitted Feb. 24, 2011, for U.S. Patent Application No. 13/034,430 (filed Feb. 24, 2011), *available at* <https://portal.uspto.gov/pair/PublicPair>.

Exhibit J – Excerpt from Certified File Wrapper of U.S. Patent No. 8,822,438, Patent Application No. 13/034,340 (filed Feb. 24, 2011).

1 **Exhibit K** – Johnson & Johnson, Form 10-Q (Nov. 4, 2016).

2 **Exhibit L** – Johnson & Johnson, Form 10-Q (Aug. 4, 2016).

3 **Exhibit M** – Johnson & Johnson, Form 10-Q (May 9, 2016).

4 **Exhibit N** – Johnson & Johnson, Form 10-K (Feb. 24, 2016).

5 **Exhibit O** – Elaine A. Mostaghel, *Abiraterone in the Treatment of Metastatic Castration-*
6 *Resistant Prostate Cancer*, CANCER MANAGEMENT RESEARCH (2012),
7 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3912049/>.

8 **Exhibit P** – Patent Board Grants Inter Partes Review of Cancer-Fighting Therapy, 24-1
9 MEALEY’S(R) LITIG. REP.: PATENTS 12 (2016).

10 **Exhibit Q** – Dr. Cary Millner & Kunyong Yang, *United States: PTAB Institutes Separate*
11 *IPR Proceedings Filed By Codefendants, Finding That The Later IPR Proceeding Was Not Barred*
12 *by 35 U.S.C. § 325(d)*, PTAB Litigation Blog, MONDAQ BUS. BRIEFING (Feb. 7, 2017).

13 **Exhibit R** – Zytiga To Face Challenges, BUSINESS MONITOR ONLINE (Nov. 3, 2016).

14 **Exhibit S** – Jan Berger et al., *How Drug Life-Cycle Management Patent Strategies May*
15 *Impact Formulary Management*, 22 (16 supp.) AJMC (Jan. 20, 2017),
16 [https://www.ajmc.com/journals/supplement/2016/how-drug-life-cycle-management-patent-](https://www.ajmc.com/journals/supplement/2016/how-drug-life-cycle-management-patent-strategies-may-impact-formulary-management/a636-article)
17 [strategies-may-impact-formulary-management/a636-article](https://www.ajmc.com/journals/supplement/2016/how-drug-life-cycle-management-patent-strategies-may-impact-formulary-management/a636-article).

18 **Exhibit T** – Silas Inman, *FDA Approves Pre-Chemo Enzalutamide for mCRPC*, ONCLIVE
19 (Sept. 10, 2014), [https://www.onclive.com/web-exclusives/fda-approves-pre-chemo-enzalutamide-](https://www.onclive.com/web-exclusives/fda-approves-pre-chemo-enzalutamide-for-mcrpc)
20 [for-mcrpc](https://www.onclive.com/web-exclusives/fda-approves-pre-chemo-enzalutamide-for-mcrpc).

21 **Exhibit U** – Donald L. Trump, *FDA Approves Enzalutamide for Metastatic Castration-*
22 *Resistant Prostate Cancer*, HEMONC TODAY (Sept. 25, 2012),
23 [https://www.healio.com/hematology-oncology/prostate-cancer/news/print/hemonc-](https://www.healio.com/hematology-oncology/prostate-cancer/news/print/hemonc-today/%7B9c47a439-aef9-4380-bdce-0e6843a2d524%7D/fda-approves-enzalutamide-for-metastatic-castration-resistant-prostate-cancer)
24 [today/%7B9c47a439-aef9-4380-bdce-0e6843a2d524%7D/fda-approves-enzalutamide-for-](https://www.healio.com/hematology-oncology/prostate-cancer/news/print/hemonc-today/%7B9c47a439-aef9-4380-bdce-0e6843a2d524%7D/fda-approves-enzalutamide-for-metastatic-castration-resistant-prostate-cancer)
25 [metastatic-castration-resistant-prostate-cancer](https://www.healio.com/hematology-oncology/prostate-cancer/news/print/hemonc-today/%7B9c47a439-aef9-4380-bdce-0e6843a2d524%7D/fda-approves-enzalutamide-for-metastatic-castration-resistant-prostate-cancer).

26 **Exhibit V** – Amit Bahl et al., *Second-Line Treatment Options in Metastatic Castration-*
27 *Resistant Prostate Cancer: A Comparison of Key Trials with Recently Approved Agents*, CANCER
28 TREATMENT REVIEWS (Aug. 16, 2013), <https://doi.org/10.1016/j.ctrv.2013.06.008>.

1 **Exhibit W** – H. Lee Moffitt Cancer Ctr. & Res. Inst., *Researchers Identify Inhibitor that*
2 *Overcomes Drug Resistance in Prostate Cancer*, SCIENCE DAILY (June 12, 2017),
3 www.sciencedaily.com/releases/2017/06/170612124417.htm.

4 **Exhibit X** – Emmanuel S. Antonakaris, *Current Understanding of Resistance to*
5 *Abiraterone and Enzalutamide in Advanced Prostate Cancer*, CLINICAL ADVANCES IN
6 HEMATOLOGY & ONCOLOGY (May 2016), [http://www.hematologyandoncology.net/archives/may-](http://www.hematologyandoncology.net/archives/may-2016/current-understanding-of-resistance-to-abiraterone-and-enzalutamide-in-advanced-prostate-cancer/)
7 2016/current-understanding-of-resistance-to-abiraterone-and-enzalutamide-in-advanced-prostate-
8 cancer/.

9 **Exhibit Y** – Andrew Pollack, *New Drug For Prostate Cancer Gets F.D.A. Nod*, N.Y.
10 TIMES (Aug. 31, 2012), [https://www.nytimes.com/2012/09/01/business/fda-approves-prostate-](https://www.nytimes.com/2012/09/01/business/fda-approves-prostate-cancer-drug.html)
11 cancer-drug.html

12 **Exhibit Z** – Naoki Terada et al., *Exploring the Optimal Sequence of Abiraterone and*
13 *Enzalutamide in Patients with Chemotherapy-Naïve Castration-Resistant Prostate Cancer: The*
14 *Kyoto-Baltimore Collaboration*, 24 Int'l J. of Urology (Apr. 28, 2017),
15 <https://doi.org/10.1111/iju.13346>.

16 **Exhibit AA** – Dennis Thompson, *Early Chemo May Boost Survival in Advanced Prostate*
17 *Cancer*, WEBMD (May 14, 2015), [https://www.webmd.com/prostate-cancer/news/20150514/early-](https://www.webmd.com/prostate-cancer/news/20150514/early-chemo-may-boost-survival-in-advanced-prostate-cancer#1)
18 chemo-may-boost-survival-in-advanced-prostate-cancer#1.

19 **Exhibit BB** – Todd Campbell, *Can Xtandi Become the Go-To Prostate Drug?*, AOL
20 FINANCE (Sept. 20, 2013), [https://www.aol.com/article/finance/2013/09/20/can-xtandi-become-the-](https://www.aol.com/article/finance/2013/09/20/can-xtandi-become-the-go-to-prostate-drug/20725994/#)
21 go-to-prostate-drug/20725994/#.

22 **Exhibit CC** – Andrew Pollack, *New Drugs Fight Prostate Cancer, but at High Cost*, N.Y.
23 TIMES (June 27, 2011), <https://www.nytimes.com/2011/06/28/health/28prostate.html>.

24 **Exhibit DD** – *What Is ZYTIGA® (Abiraterone Acetate)?*, ZYTIGA® (archived October 15,
25 2017), <https://web.archive.org/web/20171015195728/https://www.zytiga.com/>.

26 **Exhibit EE** – *How should I take XTANDI?*, XTANDI® (archived October 6, 2017),
27 <https://web.archive.org/web/20171006005848/https://www.xtandi.com/>.

1 **Exhibit FF** – *Why make JEVTANA your next step?*, JEVTANA® (archived October 5, 2017),
2 <https://web.archive.org/web/20171005083102/http://www.learnaboutjevtana.com/>.

3 **Exhibit GG** – Dep’t of Veterans Affairs, National Acquisition Center (CCST), Item
4 Details: 57894-0150-12,
5 <https://www.va.gov/nac/Pharma/Details?NDC=57894015012&CNT=V797P-5230B> (last visited
6 Feb. 25, 2019).

7 **Exhibit HH** – U.S. Dep’t of Veterans Affairs, National Acquisition Center (CCST), Item
8 Details: 57894-0195-06;
9 <https://www.va.gov/nac/Pharma/Details?NDC=57894019506&CNT=V797P-5230B> (last visited
10 Feb. 25, 2019).

1 **MEMORANDUM OF POINTS AND AUTHORITIES**

2 When evaluating a motion to dismiss, courts “may properly take judicial notice of material
3 attached to the complaint and of matters in the public record.” *Vazquez v. Select Portfolio*
4 *Servicing*, No. 13-CV-03789-JST, 2013 WL 5770995, at *1 (N.D. Cal. Oct. 23, 2013). Courts may
5 also “judicially notice a fact that is not subject to reasonable dispute,” because it “can be accurately
6 and readily determined from sources whose accuracy cannot reasonably be questioned.” Fed. R.
7 Evid. 201(b).

8 Here, the attached Exhibits fall within categories of documents that courts have recognized
9 as judicially noticeable. Courts can take judicial notice of such materials to determine whether a
10 qualifying public disclosure occurred, without converting the motion to dismiss into one for
11 summary judgment. *See, e.g., U.S. ex rel. Hong v. Newport Sensors, Inc.*, 728 F. App’x 660, 661
12 (9th Cir. 2018) (affirming judicial notice of documents “submitted to demonstrate public
13 disclosure”); *Amphastar Pharm. Inc. v. Aventis Pharma SA*, No. EDCV-09-0023-MJG, 2012 WL
14 5512466, at *3–4 (C.D. Cal. Nov. 14, 2012); *U.S. ex rel. Ambrosecchia v. Paddock Labs., LLC*,
15 855 F.3d 949, 954–55 (8th Cir. 2017) (“amended public disclosure bar is appropriately resolved on
16 a motion to dismiss, even assuming that it no longer poses a jurisdictional question” and “[i]n
17 evaluating whether the public disclosure bar applies, [courts] may consider ... items subject to
18 judicial notice.” (quotations omitted) (citations omitted)).

19 Exhibits A through H are judicially noticeable because they are “documents incorporated
20 by reference in a complaint or upon which a complaint necessarily relies.” *In re Kalobios Pharm.,*
21 *Inc. Sec. Litig.*, 258 F. Supp. 3d 999, 1003 (N.D. Cal. 2017). “Although generally the scope of
22 review on motion to dismiss for failure to state a claim is limited to the Complaint, a court may
23 consider evidence on which the “complaint ‘necessarily relies’ if: (1) the complaint refers to the
24 document; (2) the document is central to the plaintiffs’ claim; and (3) no party questions the
25 authenticity of the copy attached to the 12(b)(6) motion.” *Daniels-Hall v. Nat’l Educ. Ass’n*, 629
26 F.3d 992, 998 (9th Cir. 2010).

27 Exhibits A and B are the two patents upon which Relator’s Amended Complaint (“AC” or
28 “Complaint”) relies. Exhibit C is Defendants’ June 4, 2013 patent-prosecution filing submitted in

1 Application No. 13/034,340 (“the June 4 Submission”) and referenced in the Complaint. *See* AC
 2 ¶¶ 75, 80. The June 4 Submission is central to Relator’s Complaint, because the Complaint alleges
 3 that Defendants made fraudulent misrepresentations and/or omissions to the United States Patent &
 4 Trademark Office (“USPTO”) in that submission. Exhibits D, E, and F are *inter partes* review
 5 petitions cited by Relator in his Complaint. *Id.* ¶ 92. Exhibit G is an American Urology
 6 Association guideline from 2013 on which Relator premises one of his allegations. *Id.* ¶ 80(d).
 7 Exhibit H is a General Services Administration solicitation document from which Relator quotes in
 8 support of his claim. *Id.* ¶ 107.

9 Exhibits I through Z and AA through FF are judicially noticeable because they are “matters
 10 of the public record.” *Reyn’s Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 742, 746 n.6 (9th Cir.
 11 2006). Exhibits I and J are documents that were submitted by Defendants during the ’438 patent
 12 prosecution and are available via the USPTO’s Patent Application Information Retrieval System
 13 (“PAIR”). Courts may take judicial notice of information available from PAIR. *E.g.*,
 14 *TransCardiac Therapeutics, Inc. v. Yoganathan*, 15 F. Supp. 3d 1364, 1372 n.12 (N.D. Ga. 2014);
 15 *RB Rubber Prods., Inc. v. ECORE Int’l, Inc.*, No. 3:11-cv-319-AC, 2012 WL 860416, at *5 (D. Or.
 16 Mar. 13, 2012). Exhibits K, L, M, and N are publicly filed 10-Q and 10-K disclosures. SEC
 17 filings are subject to judicial notice. *See Dreiling v. Am. Express Co.*, 458 F.3d 942, 946 (9th Cir.
 18 2006).

19 Exhibits O through Z and AA through CC are fifteen online articles or reports that are
 20 available to the public. Defendants request these documents to be judicially noticed “not for the
 21 truth of the information,” but “merely to show that the information was publicly available.” *Hong*,
 22 728 F. App’x at 661 (upholding district court’s judicial notice of “the fact of the seven documents’
 23 public availability”) (emphasis omitted). “Courts may take judicial notice of publications
 24 introduced to ‘indicate what was in the public realm at the time, not whether the contents of those
 25 articles were in fact true.’” *Von Saher v. Norton Simon Museum of Arts at Pasadena*, 592 F.3d
 26 954, 960 (9th Cir. 2009) (citation omitted).

27 Exhibits DD, EE, and FF are three webpages from October 2017, accessed via the Wayback
 28 Machine, an internet archive that reflects how a given webpage appeared at a prior point in time.

1 “Courts have taken judicial notice of the contents of web pages available through Wayback
 2 Machine as facts that can be accurately and readily determined from sources whose accuracy
 3 cannot reasonably be questioned.” *Erickson v. Nebraska Mach. Co.*, No. 15-CV-01147-JD, 2015
 4 WL 4089849, at *1 (N.D. Cal. July 6, 2015).

5 Exhibits GG and HH are webpages published by the Department of Veterans Affairs
 6 website that reflect that Zytiga is offered for sale to the government on a Federal Supply Schedule.
 7 The Court can “take judicial notice of [p]ublic records and government documents available from
 8 reliable sources on the internet, such as websites run by the governmental agencies.” *Hadley v.*
 9 *Kellogg Sales Co.*, 243 F. Supp. 3d 1074, 1088 (N.D. Cal. 2017) (citation and internal quotation
 10 omitted).

11 Because all of the exhibits referenced herein are judicially noticeable, Defendants
 12 respectfully request the Court to take judicial notice of each of the attached Exhibits for purposes
 13 of showing the existence of the Exhibits and their date of publication.

14 Dated: February 25, 2019

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